DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Pour-On

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–299 for Ivermectin Pour-On for Cattle. The application provides for topical use of 0.5 percent ivermectin solution on cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, horn flies, lice, and mites. Med-Pharmex's Ivermectin Pour-On for Cattle is approved as a generic copy of Merial Limited's IVOMEC® (ivermectin) Pour-On for Cattle, approved under NADA 140–841. ANADA 200–299 is approved as of December 28, 2000, and the regulations in § 524.1193 (21 CFR 524.1193) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 524.1193 is further revised to reflect current format and to reflect the expiration of 3 years of marketing exclusivity granted to Merial Ltd,. in 1997 (62 FR 38907, July 21, 1997), for which revisions were made to § 524.1193 (63 FR 44384, August 19, 1998).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1193 is amended in paragraph (a) by adding "(mL)" after "milliliter"; by revising paragraph (b); by redesignating paragraph (d) as paragraph (e) and by adding new paragraph (d); and by revising redesignated paragraph (e) to read as follows:

§ 524.1193 Ivermectin pour-on.

* * * * *

(b) *Sponsors*. See Nos. 050604, 051259, and 059130 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

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(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*. (1) *Amount*. One mL per 22 pounds of body weight.

(2) *Indications for use in cattle*. It is used topically for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum*; (adults) *O. venulosum*, *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Chorioptes bovis*, *Sarcoptes scabei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalina bovis*, *Solenoptes capillatus*; horn flies *Haematobia irritans*. It is also used to control infections of gastrointestinal roundworms *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

(3) *Limitations*. Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Dated: 2/12/01
February 12, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S